Claims

What is claimed is:

1. A balloon for a medical device formed from a length of polymer tubing by radial expansion of the tubing under pressure, the polymer being a block copolymer thermoplastic elastomer characterized as follows:

the block copolymer comprises two or more hard segments of a polyester or polyamide and two or more soft segments of polyether;

the polyester hard segments are polyesters of an aromatic dicarboxylic acid and a C_2-C_4 diol,

the polyamide hard segments are polyamides of C_6 or higher carboxylic acids and C_6 or higher organic diamines or of C_6 or higher aliphatic ω-amino-α-acids, and

the polyether soft segments are polyethers of C_2-C_{10} diols,

the block copolymer has a flexural modulus of less than about 150,000 psi;

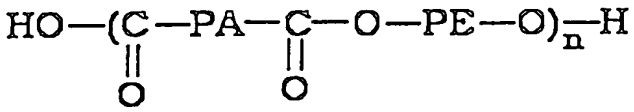
the block copolymer has a hardness, Shore D scale, of greater than 60; and

the percentage by weight of the block polymer attributable to the hard segments is between about 50% and about 95%.

2. A balloon as in claim 1 wherein the block copolymer has a Shore D hardness in the range of 65-75 and a flexural modulus in the range of 50,000-120,000 psi.

3. A balloon as in claim 1 wherein the hard segments of the block copolymer are polyamide segments.

4. A balloon as in claim 3 wherein the block copolymer is represented by the formula:



in which PA is a polyamide segment of molecular weight in the range of 500-8,000; PE is a polyether segment of molecular weight in the range of 500-2,500 and the repeating number n is between 5 and 10.

5. A balloon as in claim 4 wherein the block copolymer segment, PA, is an aliphatic polyamide of one or more C_{10} - C_{12} aliphatic acids and one or more C_{10} - C_{12} aliphatic diamines or of a C_{10} - C_{12} aliphatic ω-amino -α- acid.

6. A balloon as in claim 4 wherein the polyamide segment, PA, is selected from the group consisting of nylon 12, nylon 11, nylon 9, nylon 6, nylon 6/12, nylon 6/11, nylon 6/9 and nylon 6/6.

7. A balloon as in claim 4 wherein the polyamide segment, PA, is nylon 12 of a molecular weight of 3,000-5,000, and the polyether segment, PE, is poly(tetramethylene ether) of molecular weight between 500 and 1250.

8. A balloon as in claim 4 wherein the polyamide segments, PA, comprise between 80 and 90% by weight of the polyamide/polyether polyester.

9. A balloon as in claim 1 wherein said polyether segment, is selected from the group consisting of poly(tetramethylene ether), poly(pentamethylene ether) and poly(hexamethylene ether).

10. A balloon as in claim 1 wherein the wall strength of the balloon is at least 15,000 psi.

11. A balloon as in claim 10 wherein the wall thickness, single wall basis, is no more than 0.0015 inches and said wall strength is greater than 18,000 psi.

12. A balloon as in claim 11 wherein said wall thickness is no more than 0.0009 inches.

13. A balloon as in claim 10 wherein said wall strength is greater than 20,000 psi.

14. A balloon as in claim 1 having a compliant to semi-compliant distension profile whereby as inflation pressure is increased from 6 atm to 12 atm, the balloon expands from a nominal diameter at the 6 atm pressure to an increased diameter at the 12 atm pressure which is at least 7% greater than said nominal diameter.

15. A balloon as in claim 14 wherein the increased diameter at 12 atm is at least 10% greater than said nominal diameter.

16. A balloon as in claim 14 wherein the increased diameter is at least 16% greater than said nominal diameter.

17. A balloon as in claim 14 having a nominal diameter of between 1.5 mm and 10.0 mm, the balloon having a burst pressure of at least 10 atm.

18. A balloon as in claim 1 having a nominal diameter of between 1.5 mm and 4.0 mm, the balloon having a burst pressure of at least 12 atm.

19. A balloon as in claim 1 wherein the hard segments of the block copolymer are polyester segments.

20. A balloon as in claim 19 wherein said polyester segments are polyesters of an acid selected from the group consisting of ortho-, meta- or para- phthalic acid, napthalenedicarboxylic acid and meta-terphenyl-4,4'-dicarboxylic acids and a diol selected from the group consisting of ethylene glycol, 1,3-propane diol and 1,4-butane diol.

21. A balloon as in claim 1 wherein the block copolymer is poly(butylene terephthalate-*block*-poly(tetramethylene oxide).

22. A balloon as in claim 1 wherein the block copolymer is further characterized by a ultimate tensile strength of at least 6,000 psi and an ultimate elongation of at least 300%.

23. A dilation catheter having a elongated tubular body, a balloon mounted on a distal end thereof and means for inflation of the balloon, wherein the balloon is a balloon as in claim 1.

24. A method of forming a balloon for a medical device, the balloon having proximal and distal waist portions and a central body portion, comprising radially expanding a length of polymer tubing under pressure, wherein said length of tubing has proximal and distal portions which are stretched to a reduced diameter and an unstretched central portion, and said radially expanding step is accomplished by expanding said tubing in a mold such that the balloon body is formed from the unstretched central portion of the tubing and the proximal and distal waist portions of the balloon are formed from the stretched proximal and distal portions of the tubing, and wherein the polymer is a block polyamide/polyether or a polyester/polyether copolymer.

25. A method as in claim 24 wherein the tubing is radially expanded at a hoop ratio of between 3 and 8.

26. A method as in claim 24 wherein the tubing is radially expanded at a hoop ratio of between 4 and 7.

27. A method as in claim 24 wherein the polymer has a Shore D hardness of at least 60 and a flexural modulus of less than 150,000 psi.

28. A method as in claim 27 wherein the polymer has an ultimate tensile strength of at least 6000 psi and an ultimate elongation of at least 300%.

29. A method as in claim 24 wherein the balloon is not heat set after said radially expanding step and the balloon obtained thereby has a wall strength of at least 20,000 psi.

30. A method as in claim 24 wherein said proximal and distal portion stretching step are performed at ambient temperature.

31. A method as in claim 21 wherein said polymer is a polyamide/polyether/polyester.